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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,280	12/29/2000	D. Scott Wilbur	33700WC005	6495

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/750,280	WILBUR ET AL.
	Examiner Lauren Q Wells	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 November 2002.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33-97 is/are pending in the application.
- 4a) Of the above claim(s) 42-54,60,61,63,68,69,71,72,75-87 and 90-97 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33-41,55-59,62,64-67,70,73,74,88 and 89 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,9</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

Claims 33-97 are pending. Claims 42-54, 60-61, 63, 68-69, 71-72, 75-87 and 90-97 are withdrawn from consideration, as they are directed toward nonelected subject matter. The Preliminary Amendment filed 6/22/01, cancelled claims 1-32 and added claims 33-96.

A telephone interview with Robert Weilacher on 1/10/03 confirmed that the IDS submitted 12/19/00, Paper No. 5, is identical to the IDS submitted 5/24/02, Paper No. 15.

#### ***Election/Restrictions***

Applicant's election without traverse of the Election of Species/Restriction Requirement in Paper No. 18 is acknowledged.

The Election of Species Requirement of the single molecule reagent was clarified in a telephone interview with Robert Weilacher on 1/9/03. The species elected is compound #44 in claim 70.

#### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 33-41, 55-59, 62, 64-67, and 70 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10, 17-19, and 21-23 of copending Application

No. 09/519998. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-41, 55-59, 62, 64-67, 70, 73-74 and 88-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrases "a derivative, mutant or fragment of avidin" and "a derivative, mutant or fragment of streptavidin" in claim 33 (lines 9 and 11) are vague and indefinite, as the metes and bounds of this claim are unascertainable. The specification does not define these terms and one of skill in the art would not be apprised of all the chemical possibilities encompassed by these phrases.

(ii) The term "capable of" in claim 33 (line 19) is vague and indefinite, as it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

(iii) The phrase "a spacer having a length of 1-25 (or 6-18) atoms or groups of atoms" in claims 55, 56, 64, 65 (lines 2-3) is vague and indefinite, as it is confusing. A length of 1-25 atoms is a drastically different length than a group of 1-25 atoms, where a group can comprise

any number of atoms. How can a group of atoms, wherein the number of atoms making up the group is not defined, be a unit of measurement?

(iv) The term “active ester” in claim 62 is vague and indefinite, as the metes and bounds of this claim are unascertainable. What differentiates an active ester from an inactive ester? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of the compounds encompassed by this phrase.

(v) Claim 70 is vague and indefinite, as a claim must begin with a capital letter and end with a period. MPEP 608.01(m). In the instant case, claim 70 lacks a period.

(vi) Claims 88-89 are vague and indefinite, as they are confusing. Does the optionally modified biomolecule refer to the biomolecule reactive moiety of claim 33? What does the phrase “the single molecule reagent according to claim 33, having at least one affinity ligand and at least one effector agent bound to the reagent” mean? Must not the reagent according to claim 33 have only one affinity ligand and one effector agent? Furthermore, must not the reagent also have one biomolecule reactive moiety. It is not clear what is being claimed. What is the conjugate comprised of?

(vii) The phrase “optionally modified biomolecule, having a desired biological property retained” in claims 88 and 89 (lines 4-5) is vague and indefinite. What is an optional modification to a biomolecule. The specification does not define this and one of ordinary skill in the art would not be apprised of its meaning, as there are an incredible number of ways to modify a biomolecule. What does “desired biological property retained” mean? The specification does not define this phrase and one of skill in the art would not be apprised of its meaning.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-35, 39-41, 55-59, 62, 64-67, 73-74, and 88-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilbur et al. (WO 97/29114).

Wilbur et al. disclose biotin containing compounds and biotinylation reagents incorporating soluble linker moieties. Exemplified is a trifunctional reagent comprising tricarboxybenzene as the trifunctional cross-linking agent, biotin as the affinity ligand, maleimide as the biomolecule reactive moiety, iodinated benzene as the effector agent, and trioxadiamine as linker 1, linker 2, and linker 3. Thus, Wilbur et al. and the instant invention both teach a single molecule reagent of structure (I). See pages 38-39.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, in the instant case, the intended use of the reagent is not afforded patentable weight.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-38, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbur et al. as applied to claims 33-35, 39-41, 55-59, 62, 64-67, 73-74 and 88-89 above, and further in view of Griffiths (5,482,698).

The instant invention is directed toward a single molecule reagent comprising a trifunctional cross-linking moiety, an affinity ligand, a biomolecule reactive moiety, an effector agent, and optionally three linkers.

Wilbur et al. is applied as discussed above. The reference lacks homobiotin as the affinity ligand, wherein homobiotin contains 1 additional "CH2" member in the biotin alkyl chain.

Griffiths teaches detection and therapy of lesions with biotin/avidin polymer conjugates. The reference teaches that commercial biotin products are available in which the biotin has been modified by the addition of alkyl groups to alter the binding capacity of biotin. See Col. 8, lines 39-45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the biotin of Wilbur et al. as homobiotin because a) Wilbur et al. teach that many modified forms of biotin have been synthesized for various applications, such as providing reversible binding to a biomolecule, and are useful in their invention, and Griffiths teaches that the addition of a -CH2- group to biotin is a known commercial product that is relied upon to change the binding properties of biotin; b) a homologous series is a family of chemically related compounds, the composition of which varies from member to member by CH2 \* \* \*, wherein

Chemists knowing the properties of one member would in general know what to expect in adjacent members (In re Henze, 85 USPQ 261, 261 (CCPA 1950)); thus, one of skill in the art would have been motivated to teach biotin as homobiotin a) because of the expectation of achieving reversible binding and b) because adjacent homologs are considered to be obvious absent unexpected results.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
January 22, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

1/23/03